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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,697	08/14/2002	Ajay Kumar Luthra	16230-8677	8586

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/980,697

Applicant(s)

LUTHRA ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment dated 12/27/06.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 39,41,43-45,47-49,51-54,56-63 and 66 rejected under 35 U.S.C. 102(b) as being anticipated by Olstein (USPN 5,142,010 hereafter '010). The claims are drawn to a polymeric biguanide and a method of making the same.

3. The '010 patent teaches a polymeric biguanide formulation where one of the nitrogen atoms is bond by an amine linkage (col. 2, lin. 15-65). The polymer formed is infection resistant and is useful in bulk polymers and copolymers (col. 3, lin. 49-65). The polymeric material is incorporated into various forms useful in or on the human body and as a coating, or an implantable medical device (col. 4, lin. 54-65; col. 13, lin. 21-36). The reaction sites binding to the polymer include isocyanate (col. 2, lin. 56-60). The polymers are subsequently blended with other polymers such as acrylic acid derivatives and methacrylate derivatives (col. 9, lin. 50-65). The formation of the polymer requires a polymerization process (col. 10, lin. 51-68). The polymers are combined with polymers useful for ocular lenses such as silicones (col. 12, lin.20-25). Though the reference discloses the combination of polymeric biguanides with silicon reactive polymers, and other polymers useful for intra-ocular lenses, it is the position of the

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Examiner that such claim limitations are merely a future intended use. Where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

4. Regarding the coupling agent it is the position of the Examiner that such limitations do not impart patentability on the claims barring a showing of criticality to the couple agent. The products made by the method are identical and function in the same way. Applicant is invited to provide evidence of patentable distinction between the products made by the method of the prior art and those of the instant claims. Until such evidence can be provided the claims remain anticipated.

5. Regarding the limitation to the secondary amine nitrogen atoms, it is the position of the Examiner that this limitation does not distinguish over the art. Firstly the compound of the instant claims does not have secondary amine nitrogen atoms. The linkages are amidine nitrogen linkages. Further as described in the specification, the "secondary amine nitrogen" linkages can occur at $>C=NH$ or an $C-NH-C$ bond within the structure. This $C-NH-C$ linkage occurs in the '010 patent in example V via the phenylene group attached the NH.

6. For these reasons the claims are anticipated by the '010 reference.

7. Claims 39,41,46,50 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Buckley et al (GB 1,531,717 hereafter '717). The claims are drawn to a polymeric biguanide and a method of making the same.

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8. The '717 patent teaches a polymeric biguanide and method of making the same comprising isolating a substantially free base of a biguanide and bonding with a polymer (page 3, lin. 1-10). The polymer bound to the nitrogen of the biguanide can be an aliphatic-aromatic radical having two or more amide or urea linkages (page 1, lin. 25-30). The formulation can take various forms including solid bulk, powder or liquid form. These forms represent a medical device form.
9. Regarding the secondary amine limitation, it is the position of the Examiner that these limitations do not impart patentability to the claims. The formulation does not contain secondary amine nitrogen atoms, rather amidine nitrogen atoms. The specification defines the possible linkages that may be $>C=NH$ and possibly $C-NH-C$, without defining what they may not be. Polymer linkages disclosed in the claims of the '717 patent meet the limitations of the claims as defined by the specification.
10. For these reasons the '717 patent anticipates the claims.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 40,42,48, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures Olstein (USPN 5,142,010 hereafter '010) and Solomon et al (USPN 5,451,424 hereafter '424). The claims are drawn to a polymeric biguanide and a method of making the same.

14. As discussed above the '010 patent discloses a biguanide polymeric material yet is silent to the specific biguanide used. The inclusion of a specific biguanide is well within the level of skill in the art as seen in the '424 patent.

15. The '424 patent discloses a biguanide polymer comprising chlorhexidine (abstract). The biguanide is bound to polyurethane and used for medical tubing (example 1). Polyurethane is one of the many polymers used in grafting the biguanides of the '010 patent, therefore a skilled artisan would be motivated to include the biguanides of the '424 into the preparation of the '010.

16. Regarding the coupling agent it is the position of the Examiner that such limitations do not impart patentability on the claims barring a showing of criticality to the couple agent. The products made by the method are identical and function in the same way. Applicant is invited to provide evidence of patentable distinction between the products made by the method of the prior art and those of the instant claims. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught

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by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

17. With these things in mind it would have been obvious to incorporate the biguanides of the '424 patent into the preparation of the '010 in order to fight a wide range of bacterial infections. One of ordinary skill in the art would have been motivated to combine the teachings and references with an expected result of an infection resistant polymer.

Response to Arguments

18. Applicant's arguments filed 12/27/06 have been fully considered but they are not persuasive. Applicant argues that:

- a. The '010 patent does not disclose the polymeric material of the instant claims.
- b. The '717 patent does not disclose the polymeric material of the instant claims.
- c. The combination of the '010 and the '424 patent is not proper and does not obviate the claims.

19. Regarding argument a., as discussed above the formulation as claimed does not have secondary amine nitrogen atoms. Further as described in the specification the limitation is met by any $>C=NH$ or $C-NH-C$ bonds found along the chain. The '010 patent discloses such a linkage in example V by using the C in the phenylene group. Since any $C-NH-C$ group meets the limitations of the claims as defined by the specification the '010 patent indeed teaches each and every limitation of the instant claims implicitly and inherently as required by the statute. Applicant argues that since the linkages are different the resulting compositions will have

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different properties, yet the claimed property is to a biocidal polymer, and the prior art disclose an identical property and function. For these reasons the claims remain anticipated.

20. Regarding argument b., as discussed above the '717 patent meets the limitations of the claims. The '717 patent teaches a biguanide compound with linkages to along to another polymer at position X where X is $(CH_2)_6$. The claim limitations are met by linking along any C-NH-C group as defined by the specification, and the '717 discloses such a linkage at page 2. Using the carbon atom the linkage is complete and the claim limitations are met. For these reasons the claims remain anticipated.

21. Regarding argument c., the combination of the '010 and the '424 patent is proper and continues to obviate the claims. Applicant argues that since the compounds of the '424 patent are physically bound to the polymer unlike the chemical bonds of the '010 patent the reference cannot be used together and do not obviate the claims. However it is the position of the Examiner that since both references solve the same problem of disinfecting a polymers using similar compounds, the linkages would be an obvious manipulation by those of ordinary skill. The compounds are chemically bound to the polymer as disclosed above, and following this suggestion the compound of the secondary reference would also be chemically bound. For these reasons at least the claims remain obviated by the combination of the art.

Conclusion

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

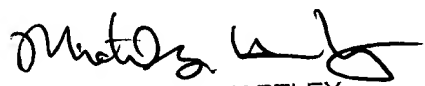
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MP Young

Micah-Paul Young
Examiner
Art Unit 1618



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER